REMARKS

The single independent claim in the application defines two error signals, each of which is a function of the same target value and a respective one of two ventilation measures. The two ventilation measures have different speeds of response. The claim goes on to define how the two control responses are combined and when each control response is favored so that it has a greater effect on the overall pressure control response.

The main reference cited by the Examiner is Cotner et al. As will be discussed in detail below, this patent describes a system which has just one error signal, not two as asserted by the Examiner. The Cotner et al. system does not have two ventilation measures with different speeds of response. It therefore cannot possibly have a mechanism for choosing one response speed over the other. The single independent claim in issue has little to do with Cotner et al.

Claim 112 refers to a target ventilation, a fast responding measure of ventilation, a slow responding measure of ventilation, and respective fast and slow errors in ventilation with respect to the target ventilation.

The Examiner states "normal inhalation as a target value". Not only is the statement unclear as to which element of Cotner et al. the Examiner equates to the claimed target ventilation, but there is in fact nothing in Cotner et al. that could even be the claimed target ventilation.

Neither of the signals M and R can be the claimed target ventilation, first because neither represents ventilation, and second because both are measures of the actual behavior of the patient, as opposed to a target behavior that a servo-controller seeks to produce in the patient. The signal M is a pressure measurement, not a target value and not a ventilation quantity, and the signal R is simply a time-lagging M signal.

The Examiner refers to the two signals M and R shown in Fig. 2a of Cotner et al. and seems to treat the Cotner et al. system as a type of servo whose output is governed by an input, with the output being controlled by an error signal that is dependent on the difference between the output and the input. But not only are signals M and R not measures of ventilation or ventilation error (which the subject claims require), in Cotner et al. neither signal M nor signal R is even a measure of error. One signal is simply a delayed version of the other and they do not have anything resembling a servo relationship.

Furthermore, the control response defined in claim 112, the only independent claim in the application, is the control of pressure. The faster speed of response results in a change of pressure that is faster than the change in pressure that results from the slower speed of response. There is nothing in Cotner et al. about different rates at which the pressure is changed.

An important thing to observe about claim 112 is the symmetry that is maintained. There are two error signals, each of which is a ventilation measure. Each ventilation measure is characterized by a speed of response. There are two control responses (to respective ones of the two error signals). The claim defines which control response is favored under which conditions, but the control responses are independent and comparable. In Cotner et al., signals M and R cannot possibly be comparable in the sense of responding to events independently and controlling responses independently since signal R is derived directly from signal M. Signal R is simply a filtered version of signal M.

In the Cotner et al. system, what the Examiner calls two error signals and two control responses are very different, even according to the way that the Examiner described them. As we shall see, the two of them are not even remotely comparable. There is really only one error signal and one control response. What the Examiner denominates as the second error signal and control response are nothing more than a circuit to make sure that the single error signal circuit operates properly (by not allowing a short breath to be interpreted as a normal breath).

The Examiner's description of how the Cotner et al. circuit operates is not correct. Before going over the long Office Action and discussing why the Examiner's description is inaccurate, the correct operation of the circuit will first be described. The following discussion will emphasize how Cotner et al. has only one error signal that controls pressure changes since the alleged presence of two error control signals was the focus of the Examiner's Action.

Sensor 28 is called a flow sensor, although the output is actually a pressure signal. The signal is fed directly through filter 23 to a first input of comparator 24. The signal is also fed to "dynamic reference tracking circuit" 25. Although in the previous response filed by applicant it was said that this filter circuit derives an average value of the sensor signal, the Examiner devotes page 13 of the Office Action to explain that the circuit simply delays the sensor signal. (The circuit operation can be described either way. The output of a low-pass filter is a moving near-term average of the filter's input signal.) The delayed signal is fed to the second input of the comparator. It is thus apparent that when the sensor signal is increasing, the signal at the first input of the comparator is greater than the delayed signal at the second input. For this condition, the comparator output remains low.

But when the breathing phase changes, the current signal drops below the delayed signal, and the comparator output goes high. If the patient's airway is open, then the comparator output goes high during every breath. If there is no high output for 8 seconds, it is assumed by Cotner et al. that this is an indication of a closed airway and the pressure is increased to open the airway. The details of the circuit are not really important. What is important is that even if the circuit described is called an error circuit, the way it operates is that the absence of an output pulse for 8 seconds indicates that the patient's airway is closed.

If the patient's airway narrows right after the start of a breath, the comparator will generate a very short positive pulse as shown in Fig. 2b (the reference is to the second pulse on the horizontal axis). This short pulse is said to be indicative of a less-than-full breath, and it should not restart the 8-second

timing cycle in progress. So the circuit is designed to ignore the short pulse (i.e., not to recognize it during the 8-second interval during which the absence of a pulse indicates the need for corrective action by increasing the pressure). The antifalsing circuit 17, a filter, gets rid of the short blip so that it is not recognized as representing a breath.

The antifalsing circuit thus simply insures that the single circuit that is said to recognize an airway closing operates to detect only breaths that exceed a certain minimum duration. The antifalsing circuit is not in some kind of control loop for controlling a response to anything. Recall that it is positive pulses at the output of the comparator that indicate airflow, that is, as long as there is a comparator output pulse at least every 8 seconds, it is assumed that there is no problem. As Cotner et al. say in column 6, lines 59-64, "[t]he circuit 17 slow[s] down the output of the differential operational amplifier [comparator] in the inhalation detector 24 to prevent short duration pulses, which characterize 'critical flow limitations' (reduced inhalation), from being sensed as normal inhalation."

In short, even if the absence of a pulse for 8 seconds is considered to be an "error signal" (a very expansive interpretation of the term "error signal"), there would still be only one error signal in Cotner et al. that controls a change in pressure, not two. As for the claimed "target value," what the Examiner has selected in Cotner et al. for this parameter will be discussed below, but since there is only one error signal, it follows that there cannot possibly be two error signals that are both functions of the same target value as the claim requires. Even if there is a ventilation measure (it is not clear what it would be) in Cotner et al., there would be only one, not two. There is only one speed of response, not two. Since there is only one error control signal, not two, it is meaningless to talk about one control response being favored over the other in Cotner et al., and it is certainly meaningless to talk about how the favoritism changes. There is practically nothing in the independent claim in issue that applies to the reference.

We turn now to the Examiner's analysis of the reference circuit.

The material starting at the bottom of column 6 of Cotner et al. and the material in column 8 do describe an error control (once again, only with an expansive interpretation of "error"), as the Examiner indicates on page 2 of the Office Action. But column 6, lines 56-64, and column 8, lines 11-26 and 42-60, do not describe a second error control signal. This material describes how the antifalsing circuit simply prevents erroneous operation of the single error control circuit. The paragraph in column 6 identified by the Examiner includes the quote given above -- what the Examiner is calling a second error signal does not control a pressure change. Rather, it is included in the circuit "to prevent short duration pulses ... from being sensed as normal inhalation." And the material in column 8 identified by the Examiner is equally explicit:

> FIG. 2C shows how the time delay in the antifalsing circuit 17 modifies the signal sent to the timing circuit 27 by delaying the leading edge "E" of the square wave and totally eliminating the false inhalation detection wave "P" indicated in FIG. 2b.

The Examiner's "second error signal" eliminates false inhalation detection (short breaths), but is not a signal that is in competition for control with a first error signal, and there are no rules for deciding which of two signals is favored.

On page 2 of the Office Action, the Examiner considers the "target value" of the claim. It is really a stretch to say that the target value of the claim can be nothing more than "normal inhalation" as the Examiner contends, but let us assume that this is the case. With such an expansive interpretation of the claim language, it can be said, as the Examiner does, that the first (really, the only) error signal is a function of a target value because it represents that the target value (normal inhalation) has not been reached. But the Examiner goes on to say that "Col 8 lines 42-60 disclose that the second error signal indicates false inhalation, or lack of normal inhalation as target value," and this is absolutely incorrect.

What this material says explicitly is that what the Examiner is calling the second error signal "modifies" what the Examiner has identified as the first error signal so that the first error signal correctly identifies inhalation or the lack

thereof. In Cotner et al., there is no second error signal that is a function of normal inhalation (what the Examiner calls the target value). The so-called second error signal is not even an error signal; it simply makes sure that the single error signal operates correctly.

It is not just a question of what the Examiner calls a second error signal not controlling anything that returns the system to a target value. Even what the Examiner calls a target value -- normal inhalation -- is not really a target value. On page 9 of the Office Action, the Examiner refers to column 9, lines 25-35, as teaching normal inhalation as a target value. But normal inhalation in Cotner et al. has nothing to do with a ventilation measure which is what the claim in issue is about. The target value is a ventilation measure, and a ventilation measure has to do with how much air the ventilator delivers to the patient. The so-called target value in Cotner et al., according to the Examiner is nothing more than a breath at least once every 8 seconds. This would not be taken by anyone as a "measure of ventilation" as called for by the claim.

The Examiner next considers the two ventilation measures of the claim and identifies column 6, lines 44-67, as referencing "the output of flow sensor 28 and the output of dynamic reference circuit 25 as two ventilation measures." But in fact the two outputs are based on the same flow measure. It is just that one is filtered and lags the other. (See column 6, lines 22-24.) There is only one ventilation measure in Cotner et al., and it is the output of the flow sensor. It is improper for the Examiner to take sequential signals in a processing chain and to say that they are different ventilation measures when in fact they are based on only a single measure.

Applicant also takes issue with the next assertion in the Office Action. Starting with what are <u>not</u> two different ventilation measures, the Examiner proceeds to argue that they have different response speeds. Column 6, lines 13-30, just does not say this and it is not apparent how the Examiner finds any support in this material for the argument. A little thought will reveal that it is not even possible for there to be different response speeds. Since the output of flow

sensor 28 feeds the input of dynamic reference circuit 25 (through filter 23), what does it even mean to say that they have different response speeds? How can one output get increasingly ahead of or behind the other if circuit 25 simply delays the output of circuit 28? When talking about a response speed, what is meant is how fast the response of a control circuit is to an input that represents an error. The two signals identified by the Examiner do not even represent errors, so they cannot have response speeds and they most certainly cannot have different response speeds. One output represents flow, and the other represents flow delayed in time. There is no error here to even speak of. An error indication occurs only later in the chain when comparator 24 operates and does not output a pulse for 8 seconds. The two outputs of circuits 28 and 25 do not represent errors of any kind, so they cannot possibly have different response speeds since they don't have response speeds.

Fig. 2a in Cotner et al. has two curves, the output of the flow sensor (the "M" solid curve) and the output of the dynamic reference circuit (the "R" dashed curve). It is obvious that the latter is delayed from the former as the result of filtering. The Examiner refers to the two outputs as supporting the assertion that they have fast and slow response speeds respectively, but the two curves have nothing to do with response speeds. One signal is used to make sure that the other does not cause a false inhalation pulse to be recognized, and neither even represents an error for which there could be a response. An "error" is not detected until later on in the processing chain, when an inhalation pulse is absent for 8 seconds.

The Examiner's analysis on page 3 of the Office Action regarding Fig. 3 of Cotner et al. and the description at column 9, lines 64 through column 10, line 2, and column 9, lines 12-18, also does not conform to what the reference patent actually teaches. Fig. 3 shows how a low mask pressure at the onset of a critical flow limitation (point C, what might be considered an "error") persists for only 8 seconds, at which time (point D) the pressure starts to rise. That is what the text referred to by the Examiner actually says. The Examiner translates this into point C representing a second error signal to keep the pressure low, and point D

representing the first error signal at which time the pressure goes higher, with the two control responses being combined to produce an overall response that favors increasing the pressure in response to the error signal that is a function of the ventilation measure with the faster speed of response as the ventilation measure with the faster speed of response becomes increasingly less than the target value. But all that Fig. 3 in Cotner et al. actually shows is how the pressure changes, with the interval from C to D simply showing that the pressure does not start to rise until inhalation has not been detected for 8 seconds. The figure has nothing to do with different ventilation measures, different control responses, favoring one control response over another, target values or any of the other things the Examiner has read into the drawing and description

On page 4 of the Office Action, the Examiner turns to the dependent claims. Contrary to what the Examiner says with reference to claim 113, Cotner et al. do not have two control responses as previously discussed, and there is no such thing as one response being more vigorous than the other. Causing blower speed (pressure) to increase may be more vigorous than causing it to remain constant, as the Examiner asserts. But keeping the pressure constant means that there is no error; and, if there is no error then there is no response to speak of. There is no getting away from the fact that in Cotner et al. there is just one "error" (no inhalation for 8 seconds), and there is just one control response (increase the pressure until there is inhalation).

Similar remarks apply to claims 114 and 121, the rejection of which is once again based on the erroneous supposition that Cotner et al. disclose two ventilation measures, two error signals, two control responses, and a way to favor one control response over the other.

Starting on page 5 of the Office Action, the Examiner combines Cotner et al. with two secondary references in rejecting some of the dependent claims under Section 103. That some of the features added by the dependent claims may be disclosed in the secondary references is of little moment since the basic

control structure is not shown by any of the references, not Cotner et al. and not the secondary references.

Although the argument here is more extended than that in the response to the previous Office Action, the argument here is basically the same as that previously presented. It is not until page 12 of the present Office Action, however, that it becomes apparent why the Examiner was not convinced by the earlier argument. The Examiner identifies two error signals and disputes the earlier argument which said that there is just one error signal. The end of the 8-second timing interval is said to be the first error signal, and the second error signal is said to be the critical flow limitation that indicates reduced inhalation and that is described at column 6, line 63, and column 8, lines 12-13.

Referring to column 8, lines 12-13, it will be seen that what the Examiner refers to as the second error signal is at point 5 in Figs. 2a and 2b. And it is here that the Examiner has analyzed Cotner et al. incorrectly. Referring to Figs. 2a and 2b, point 5 represents the same kind of "error" signal as point 1. Both points represent the same kind of change in breathing phase. Referring to Fig. 2a, it will be seen that at both points the solid line M and the dashed line R intersect, with the solid line going down past the dashed line. But because the second breath shown by curve M in Fig. 2a is so short, it is not considered to be a breath and should not start the 8-second timer all over again. What the Examiner is calling the second error circuit (the dynamic reference tracking circuit 25) eliminates the effect of the short pulse in Fig. 2b. This is shown in Fig. 2c where the short pulse (representing a short breath that is to be ignored by the single error-detecting circuit) is missing. Thus rather than the purported second error signal having an effect similar to that of the first error signal (and satisfying the symmetrical structure of claim 112), the second signal has the opposite effect. Every pulse from the first error circuit starts the timer all over again. The second error circuit is designed to prevent pulses at the output of the first error circuit from restarting the timer. The key sentence in the Office Action is the following at page 12:

> Therefore, the signal or indication that 8 seconds have elapsed as [sic] first error signal, and the signal or indication of a critical flow limitation are two different signals indicating a deviation from proper inhalation and both are used to control the ventilator.

This is wrong because there is only one kind of error detection in Cotner et al. -- the absence of inhalation for 8 seconds. The Examiner's second "error" signal prevents a short breath from being treated as a breath (because it is not considered to be a breath), but there is still only one kind of error detection. And certainly there is nothing in the circuit that favors one signal over the other when one signal simply modifies the other. And since the second signal controls nothing on its own, but simply affects the first signal, it makes no sense to apply the claim and say that there is a speed of response that applies to the second signal.

It is believed that the application is in a condition for allowance, and the early passage to issue of the application is respectfully requested.

Respectfully submitted
Gottlieb, Rackman & Reisman, P.C.

Dated: May, 21, 2010

By:_____
Michael I. Rackman
Attorney for Applicants
Registration No. 20,639